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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/815,297
Filing Date: March 31, 2004
Appellant(s): JEGLA, TIMOTHY JAMES

Chuan Gao
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 07, 2007 appealing from the Office action mailed on June 11, 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is essentially correct. The pending claims 12-14 and 16-18 are rejected under 35 U.S.C. §101, utility and §112, first paragraph, enablement. Applicant's statement regarding rejections of "claims 15-20" is considered to be a typographical error.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12-14 and 16-18 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility in currently available form. These claims are drawn to an isolated protein that is described in the specification as an alpha subunit of a voltage gated potassium channel and identified therein as "Kv 10.1. The text on page 63 of the instant specification, however, states that "[w]hen expressed in Xenopus oocytes, Kv 10.1 is indeed electrically silent" and that "no voltage-dependent potassium currents are detected in oocytes injected with Kv 10.1 mRNA, indicating that Kv 10.1 can't form functional voltage-gated potassium channels as a homomultimer". That text further discloses that Kv 10.1 forms functional heteromultimers with Kv2.2" that "are voltage-gated, but activate and deactivate more rapidly than Kv2.2 homomultimers". However, there is no evidence presented in the specification that a protein of the instant invention naturally forms a heteromultimeric voltage gated potassium channel in combination with Kv 2.2 or that such a combination has an established biological role in a particular

disease, disorder or physiological process which one would wish to manipulate for a desired clinical effect.

It is clear from the instant application that the protein described therein as Kv10.1 is what is termed an "orphan protein" in the art. An orphan protein is a protein encoded by a DNA that has been identified and isolated because it theoretically encodes an amino acid sequence with similarity to the sequences of one or more known proteins. Such a protein is regarded as an orphan because, whereas it can be classified with related proteins such as ion channels, receptor tyrosine kinases, G protein-coupled receptors, cytokines, chemokines, transcription factors, kinases, mixed function oxygenases, proteases, antibodies and the like, its particular physiological role has yet to be determined. There is little doubt that, after complete characterization, this protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete.

The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed "real world" utility. The court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion".

The instant claims are drawn to an isolated polypeptide of as yet undetermined biological significance. The instant specification identifies the claimed polypeptide as "Kv10.1 voltage-gated potassium channel" subunit "of the Kv (or KCNA) gene family" (top at page 3 of the instant specification). It is also disclosed that "Kv10.1 is expressed in the brain (e.g., whole brain, substantia nigra, and frontal cortex), spinal cord, prostate and retina". Because of the structural similarity of the polypeptide of SEQ ID NO: 3 to members of Kv superfamily (see Figures 1 and 2) and the functional evidence described on page 63, the specification states that the instant Kv10.1 polypeptide of SEQ ID NO: 3 represents a novel potassium channel subunit and asserts its functions as being similar to those of the members of the potassium ion channel family.

However, there is no evidence of record to support a conclusion that all potassium channels in general, and all of the members of "Kv superfamily and the Kv10 family of potassium channels" (p. 2 of the specification) in particular, share a common physiological role that can serve as a basis for a specific and substantial utility for each and every member of that family. Thus, the relationship between the instant polypeptide of SEQ ID NO: 3 and members of Kv family does not provide an apparent utility for the claimed polypeptides.

In the absence of knowledge of the biological significance of a Kv10.1 polypeptide of the instant invention, there appears to be no immediately obvious patentable use for it. Whereas the instant specification contains the assertion that "[m]odulators of Kv10.1 are useful in treating CNS disorders, such as epilepsy and other seizure disorders, Parkinson's disease, migraines, psychotic disorders such as schizophrenia and depression, cognitive disorders such as learning and memory disorders, neuropathic pain, vision disorders, prostate hyperplasia, for controlling spermatocyte maturation and motility, for treating infertility, and as contraceptive agents. Modulators are also useful as neuroprotective agents (e.g., to prevent stroke)" (page 3), there is no evidence provided to support these alleged utilities. The asserted utilities contained in the specification appear to be based solely upon the fact that a protein of the instant invention is expressed in tissues that are known to be involved with the pathologies of the named diseases and disorders. However, the instant specification fails to provide any evidence or sound scientific reasoning that would support a conclusion that the polypeptide of SEQ ID NO: 3 is causally associated with any particular disease or disorder, and one of ordinary skill in the art of molecular biology would not reasonably conclude, for example, that each and every protein that is expressed in the prostate is involved with the pathology of each and every disorder known to afflict the prostate. The instant specification, therefore, leaves it to the artisan to make the further inventive contributions that are needed to establish a nexus between the structure and/or function of a Kv10 protein of the instant invention and the etiology of a particular disease or disorder. This instant specification also leaves it to

the artisan to determine if it is the stimulation or suppression of the activity of a Kv10.1 protein that is needed to provide a beneficial effect upon the disease or disorder to be treated. It is a matter of law that an invention must have a specific and substantial utility "in currently available form", which precludes the need for further research, if that research is needed to establish or reasonably confirm a specific and substantial utility for the claimed invention (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966)),

To use a Kv10.1 polypeptide of the claimed invention in "methods of screening for activators and inhibitors of potassium channels that contain Kv10.1 subunit" (bottom at page 8) does not constitute a specific and substantial utility for that polypeptide in its currently available form because such methods are only employing that protein as the object of further research and characterization. Further, the instant application also fails to enable the use of the claimed protein as a marker that is diagnostic for a particular disease or disorder, which would be a real world utility, because it fails to describe an established difference in structure or function between Kv10.1 in healthy tissue and Kv10.1 in a diseased or dysfunctional state.

Because the instant specification has failed to establish a specific and substantial role for the claimed protein in a particular disease, disorder or physiological process which one would wish to manipulate for a desired clinical effect, one would not reasonably believe that the administration of a modulator of that polypeptide would prevent or treat a condition or disease, including CNS disorders, vision problems and psychotic disorders, as implied by the specification. Further, a specific utility in such a capacity has not been established because one can not predict if it is a Kv10.1

stimulator or a Kv10.1 inhibitor that is required to achieve a beneficial effect in the treatment of a specific disease or disorder. To employ a polypeptide of the instant invention in any of the disclosed methods would clearly be using it as the object of further research, which has been determined by the courts to be a utility, which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for the Kv10.1 polypeptide of the instant claims in its currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-14 and 16-18 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

(10) Response to Argument

At pp. 4-5 of the Brief, Appellant traverses the rejection on the premise that the rejection is in conflict with the decisions in *In re Langer* and MPEP 2107. Appellant states that the instant specification asserts a specific and substantial utility of Kv10.1

polypeptides, which is "that the identification of Kv10 subunits allows screening for modulators of voltage-gated potassium channels comprising a Kv10 subunit. Because of the involvement of known Kv channels in regulating various biological processes such as neuronal integration and cell proliferation (see, e.g., page 2, lines 15-23) and also because of the expression pattern of Kv10.1 in the brain, spinal cord, prostate and retina, it is asserted that these modulators are useful for treating disorders of the central nervous system and for modulating male fertility" (p. 6 of the Brief). Appellant's review of the issue of utility, the case law that has been cited and the holding that is found in that case law is not disputed. The only point of disagreement appears to be the interpretation of what constitutes a specific, substantial and credible utility.

The instant claims are directed to an isolated polypeptide, which is asserted to be an alpha subunit of a novel voltage-gated potassium channel, Kv10.1 of SEQ ID NO: 3. However, the instant specification, as filed, fails to identify a specific biological significance of the instant polypeptide of SEQ ID NO: 3 and/or its association with any particular disease or pathological condition to substantiate the asserted therapeutic use of modulators of the polypeptide of SEQ ID NO: 3. Furthermore, there appears to be no evidence of record presented in the instant specification that would establish the significance of modulation of Kv10 of SEQ ID NO: 3 with relation to a specific physiological activity or a particular pathological condition. Thus, the instant specification, as filed, fails to provide any evidence or sound scientific reasoning to support a conclusion that "compounds that modulate Kv10 channels [...] can be useful as therapeutic agents for treating diseases related to altered functions in tissues

expressing Kv10 channels, such as disorders of the central nervous system" (page 7 of the Brief). One skilled in the art readily appreciates that because the instant specification, as filed, has not linked the disclosed Kv10 polypeptide with any specific disease state or disorder, including disorders of the central nervous system and male fertility, there appears to be no scientific basis for concluding that a compound that modulates Kv10 would be useful for treating these diseases. One skilled in the art would be required to perform significant amount of further experimentation in order to identify a specific biological activity of Kv10, its significance to a particular disease and, further, to what "use" any information regarding compounds that modulate Kv10 of SEQ ID NO: 3 could be put. For example, if a test compound was identified as being capable of inhibiting or activating Kv10 channels (by using assays "to screen for inhibitors and activators of Kv10 channels", p. 7 of the Brief), what would that mean to the skilled artisan? Is it a potential drug, or would administering the compound be likely to acerbate the disease? Moreover, in the instant case, since the instant specification fails to present any evidence that Kv10 of SEQ ID NO: 3 is specifically associated with a particular pathological condition of central nervous system, retina or prostate, a skilled practitioner would not know which disease could be potentially treated by administration of a compound that is an agonist or antagonist of Kv10 of SEQ ID NO: 3 or whether it is the administration an agonist or the administration of an antagonist that is required to achieve a desired effect.

At pp. 6-7 of the Brief, Appellant submits that "the present invention has a substantial or "real-world" use. This invention provides Kv10 polypeptides. The

application also teaches that Kv10 channels modulate intracellular potassium concentration in certain tissues, teaches how to assay the function of Kv10 channel, and teaches how to identify modulators of Kv10 channels". The Examiner maintains that the asserted utility of the instant polypeptide of SEQ ID NO: 3 solely based on its belonging to the class of potassium channels and disclosed pattern of tissue distribution is neither specific nor apparent. It is not specific because it is merely a hypothetical possibility, an objective which the disclosed asserted potassium channel, or any ion channel for that matter, could achieve, but not one for which the claimed polypeptides have been used in the real world. It is not specific because nothing about the asserted utility sets apart this instant polypeptide expressed in brain, retina and prostate from any other potassium channel found in the same tissue. It is also not apparent because Kv channels have not been shown to share a common specific and substantial utility. The art attributes a broad variety of biological functions to different potassium channels (see the specification at p. 1, for example) and, therefore, a well-established utility cannot be immediately assigned to the instant polypeptide of SEQ ID NO: 3 solely based on its ability to "modulate intracellular potassium concentration", p. 6 of the Brief.

At pp. 7-9, Appellant discusses the Declaration of Krafte under 37 CFR 1.132 and states that "the Examiner has not provided objective reasons sufficient to rebut Dr. Krafte's Declaration". Appellant's arguments have been fully considered but are not persuasive for the following reasons.

The Declaration by Douglas Krafte under 37 CFR 1.132 filed on April 30, 2007 is insufficient to overcome the rejection of claims 12-14 and 16-18 based upon 35 U.C.S 101/112, first paragraph, for reasons set forth below.

The Declaration presents the following statements:

"The potassium channels are indicated in signal transduction during various biological processes such as neuronal integration, cardiac pacemaking, muscle contraction, hormone secretion, cell volume regulation, lymphocyte differentiation, and cell proliferation. Given this knowledge and the specific expression of Kv10.1 n the CNS, male reproductive organs, and retina, one of ordinary skill in the art would recognize the Kv10.1 channel as a therapeutic target for treating CNS or vision disorders or for regulating male infertility" (section 6 at p. 2 of the Declaration);

Since the sequence of Kv10.1 is identified, "one of ordinary skill in the art can thus conduct routine testing to identify activators or inhibitors of a Kv10.1 potassium channel useful for modulating signal transduction in the cells where this potassium channel is present (*e.g.*, the brain, spinal cord, prostate, testis, and retina), and therefore useful for treating neurological disorders and vision problems, or for modulating male infertility" (section 7 at p. 3);

"[I]t is perfectly reasonable to expect that the targeting of a Kv10.1 channel, a voltage-gated channel expressed at a high level in the CNS, ocular tissue, and male reproductive system, is an appropriate strategy for treating disorders in the CNS or vision, or conditions related to male infertility, whether or not such abnormality is directly caused by altered Kv10.1 activity" (section 8 at pp. 3-4).

Thus, the Declaration is in agreement with the knowledge in the art and the position fully explained by the Examiner in the office actions of record that the potassium channel family represents a broad class of molecules involved in variety of basic physiological processes ("neuronal integration, cardiac pacemaking, muscle contraction, hormone secretion, cell volume regulation, lymphocyte differentiation, and cell proliferation", see above). As such, the utility of this instant currently claimed Kv10.1 of SEQ ID NO: 3 channel cannot be immediately recognized by virtue of belonging to a class of molecules with a specific and well-established utility because potassium channels do not have common physiological function which supports its common practical utility. Further, there appears to be no reasonable explanation given in the Declaration or presented in the instant specification, as filed, as why one skilled in the art would recognize this instant Kv10.1 channel as being specifically associated with certain diseases of the CNS, vision disorders or with male infertility based solely on the pattern of tissue distribution of Kv10.1. Moreover, one readily appreciates that "CNS disorders and vision disorders and male infertility" represent an extremely large number of unrelated disorders of different etiologies and courses of pathology. Without knowing a biological role or physiological significance of this instant Kv10.1 channel in at least one of those disorders, a skilled practitioner would have to resort to a significant amount of further research and experimentation, not limited to "routine testing to identify activators or inhibitors of a Kv10.1 potassium channel" (section 7 of the Declaration". Clearly, disclosure of "tissue distribution for the Kv10.1 ion channel" (section 9 of the Declaration), does not provide for immediate use of the Kv10.1 in treating CNS

disorders or any other disorders, as no evidence of record has been brought forward to indicate any specific association of Kv10.1 channel with any disorder or disease.

Further, potential discovery of compounds that modulate potassium influx ("open or close of the Kv10 channels") would not lead to prevention or treatment of a condition or disease as implied by the specification because without knowing the functional significance of Kv10 of SEQ D NO: 3 one would not expect that administration of a compound that "opens or closes Kv10" would have a considerable impact on the treatment of a disease. The Examiner maintains that the specification does not disclose an established relationship between Kv10 and any specific disease or disorder, including diseases of the central nervous system and "abnormalities found in the retina (e.g., vision disorders) or prostate (e.g., male infertility)", as asserted in the instant specification. Significant further research would have to be conducted to identify diseases or disease states which correlate with a particular *in vivo* activity shown to be attributable the instant Kv10 of SEQ ID NO: 3.

At pp. 10-11 of the Brief, Appellant argues that the Examiner specifically requires Appellant to name "a specific disease or disorder [...] connected to Kv10.1" and submits that "the purported diversity in potassium channel functions and etiologies of CNS, vision, or male fertility disorders does not amount to sufficient reasons to overcome the presumption of patentable utility". Appellant's arguments have been given careful consideration but not found to be persuasive for the following reasons. To satisfy the requirement of U.C.S. § 101, the utility of the claimed invention must be both substantial, such as useful to the public for a significant and presently available benefit,

and specific, such as meaningful "real world' utility. In the instant case, the use of the polypeptide of SEQ ID NO: 3 "for treating CNS, vision, or male fertility disorders" is a recitation of a mere hypothetical possibility because without knowing any further information in regard to the specific involvement, in any, of this particular polypeptide of SEQ ID NO: 3 in at least one of the "CNS, vision, or male fertility disorders", identification of modulators of polypeptide of SEQ ID NO: 3 provides no meaningful readily available benefit to the public.

At pp. 12-13 of the Brief, Appellant compares the instant claimed invention with Example 8 of the Utility Guidelines and argues that the situation in Example 8 can be directly compared to the present application. Appellant's arguments have been carefully considered but are not persuasive for the reasons that follow.

In Example 8, a compound A, that inhibits an enzyme XYZ, to treat diseases caused or exacerbated by enzyme XYZ, has been found to have a utility because enzymes have a well established utility in the art. However, this appears to be not the factual situation here. The inhibitor of an enzyme, which has a specific association with a group of diseases ("caused or exacerbated by enzyme XYZ") obviously would have a specific and substantial credible utility as readily available to have an effect on the enzyme/disease. In the instant case, Kv10.1 potassium channel is not defined as belonging to a group of channels that are "a cause of" any group of diseases; on the contrary, the potassium channels are known to have broad range of diverse physiological functions (see section 6 of the Declaration, for example, the instant specification and reasoning above). The Examiner disagrees with Appellant's statement

that "potassium channels, like enzymes, have a well-established utility in the art: adjusting the passage of K+ according to varying physiological conditions" (p. 13 of the Brief). Modulating of potassium current across cell membrane corresponds to one of the most universal biological characteristics of a live cell. The "adjusting the passage of K+" is not known in the art to provide a well-defined and particular benefit to the public. The proper analysis of the instant claims, which are drawn to an isolated polypeptide of yet undetermined significance, should be made in light of Example 12 of those guidelines, which explains why an isolated nucleic acid encoding an "orphan receptor" lacks utility in the absence of the disclosure of a specific role for either the nucleic acid or protein in a known disease or disorder or a physiological process which one would wish to manipulate for clinical effect.

On page 10 of the Brief, Appellant urges that "a utility rejection raised in this manner is inconsistent with the proper practice described in the MPEP, which places the initial burden on the Examiner, not a patent applicant, to provide evidence to support a factual conclusion of the credibility of an asserted utility". Applicant is advised that a statement of a specific utility is treated as true if it would be believed to be true by one of ordinary skill in the art **given the evidence of record**. Because there is absolutely no evidence provided by the instant specification or the prior art of record that a subunit protein of the instant invention is involved in any specific way with "CNS disorders, such as epilepsy and other seizure disorders, Parkinson's disease, migraines, psychotic disorders such as schizophrenia and depression, cognitive disorders such as learning and memory disorders, neuropathic pain, vision disorders, prostate hyperplasia,"

"controlling spermatocyte maturation and motility" or "infertility", the utilities asserted ion page 9 of the instant specification are not credible to one of ordinary skill in the art of receptor biology in view of the evidence of record, or more precisely, the lack thereof.

Appellant's position that the USPTO is obligated to unquestionably accept any and all statements of fact in a patent application, irrespective of whether those statements are supported by any facts of record or sound scientific reasoning is erroneous. "Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant 's assertions", (M.P.E.P. 2106.02 II(b)(1)(ii)).

At p. 15 of the brief, Appellant refers to two post-filing publications brought forward during prosecution. The Examiner maintains that reliance on post-filing experiments by others to support the utility and enablement is not proper as 35 U.S.C. 101 makes it clear that the invention must be fully disclosed at the time of filing, which precludes any further experimentation to establish the utility of the claimed polypeptide. Appellant can not properly rely upon discoveries by themselves or others that are made subsequent to the filing of the instant application to complete the claimed invention. Further, publication of Singh et al., 1998 (p. 5), describes mutations in a different unrelated potassium channel, KCNQ2, and as such, the relevance of that publication to the instant claimed invention is not clear.

Appellant's reference to US application 09/833,466 has been fully considered (p. 13 of the Brief); however, it is well settled that the prosecution of one patent application

does not affect the prosecution of another application. *In re Wertheim*, 541 F.2d 257, 264, 191 USPQ 90, 97 (CCPA 1976). Accordingly, Appellant's arguments with respect to the patent application 09/833,466 are unavailing.

The Court in *Brenner v. Manson* held that "[t]he basic *pro quid quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point – where specific benefit exists in currently available form – there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." Id. at 534-35, 148 USPQ at 695. *Brenner's* standard has been interpreted to mean that "vague, general disclosures or arguments of "useful in research" or "useful as building blocks of value to the researcher" would not satisfy §101. See *Kirk*, 376 F. 2d at 945 153 USPQ at 55 (interpreting *Brenner*).

In the instant case, Appellant's invention is predicated on the finding that a polypeptide of SEQ ID NO: 3 has a structural similarity to potassium channels and it is naturally expressed in certain human tissues (CNS, retina, prostate). Appellant further extrapolates this result into an assertion of usefulness of the disclosed polypeptides (modulators thereof) to treat "abnormalities found in the CNS, retina (e.g., vision disorders) or prostate (e.g., male infertility)". However, the asserted utility of the claimed polypeptides for clinical purposes lacks support in the specification or in the evidence of record. To grant Appellant a patent encompassing an isolated polypeptide corresponding to a naturally occurring human protein, which is not readily usable in its current form, would be to grant a monopoly "the metes and bounds" of which "are not

capable of precise delineation". That monopoly "may engross a vast, unknown, and perhaps unknowable area" and "confer power to block off whole areas of scientific development, without compensating benefit to the public" *Brenner v. Manson*, Id.).

Claims 12-14 and 16-18 are also stand rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Therefore, for reasons set forth above, Appellant's arguments have been fully and carefully considered, but are not considered sufficient to rebut the *prima facie* case of lack of utility.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Olga N. Chernyshev

OLGA N. CHERNYSHEV, PH.D.
PRIMARY EXAMINER

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